Cases for Overhauling Pharmaceutical Governance

2009-03-07 09:24:00

By

On February 26, documents from the federal lawsuit against AstraZeneca's allegedly illegal marketing of the psychiatric drug Seroquel were released (available here). In the coming days and weeks, journalists and bloggers, not to mention personal injury lawyers, can be counted on to publicize the most spectacular offenses revealed by these documents.

On other fronts in the campaign against illicit pharmaceutical company activities, a landmark case broke against Wyeth in its bid to shield itself with the defense that "its compliance with the Food and Drug Administration's labeling requirements should immunize it from lawsuits". Federal regulators stepped up investigations on doctors who take kickbacks from drug companies, and Senator Charles Grassley declared war on Harvard Medical School faculty for their financial ties to industry. HMS students joined in their own protest.

News reports and critical blogging contribute to the growing popular support for oversight of pharmaceutical marketing practices and of the doctors who work with/for the industry. They cannot, however, be counted on to provide the kind of intelligence we will need to administer deep pharmaceutical governance reform. What is governance reform? Why do we need it? What must we know to design and implement it?

There are various definitions of governance. One that concisely orients us to an institutional level, such as that of a corporation, is, "the way in which an organization is run and controlled." Let's call that Definition Alpha. Another way to look at governance is as "rules, processes and behaviour that affect the way in which powers are exercised…. particularly as regards openness, participation, accountability, effectiveness and coherence." Let's call that Definition Beta. Along the lines of Definition Beta and speaking specifically of pharmaceuticals, Fox and Ward say:

"The globalisation of production and consumption challenges the ways in which potentially harmful yet essential technologies such as pharmaceuticals are governed. In modern liberal democracies, governance (a term whose Greek root implies control) depends not only on law and regulation but also on successfully engaging a wide range of

interests within society—industry, professionals, and the public—as responsible and accountable" (2005:40).

At present, society's participation in pharmaceutical governance of either type is restricted because pharmaceutical companies, as private enterprises, are legally entitled to keep most of their practices, strategies, and data (market and scientific) secret. The public's knowledge of how drugs are developed and marketed is limited. The gap between our knowledge (small) and our interest (great) is filled by trust: Trust in the FDA to oversee the approval of safe and efficacious drugs. Trust in doctors and in the system of medical education. And lastly trust even in pharmaceutical company personnel when they say that they are pursuing cures and not intentionally tricking us into taking useless, dangerous, or overpriced drugs.

That this trust is misplaced is evident right away when we examine internal company documents such as those from the Seroquel case, or those from Neurontin, Vioxx, Zyprexa and others that have come to light in recent years.

However, these documents reveal much more than just evidence of how our trust is misplaced. They permit a direct view into how pharmaceutical companies actually operate. And this will be vital to pharmaceutical governance reform, when we finally reach that stage.

Another way of putting this is to say that while the scale of the organization of deceit revealed in these documents astonishes, what should strike us the most in the depiction of the implemented marketing plans is how routine they appear to be. The spectacle of the court trial is in this sense a distraction, since it focuses our attention on violation, on breach. But while the actions under investigation may be legal contraventions, they are not managerial ones. On the contrary, the marketing practices conform to business and organizational norms that are positively embraced as sound managerial principles.

Because of this, the most florid violations lie on a simple continuum with all pharmaceutical marketing practices. The prosecuted cases are distinguished, if at all, by degree and not kind with other examples. If for no other reason than that competitive pressures drive companies to behave in similar ways, one can guarantee that the marketing strategies and tactics for drugs of a single class will resemble each other. When Vioxx blew, industry watchers knew that the other Cox-2 inhibitors (Celebrex and Bextra) were potentially not far behind. When Zyprexa was called to account, informed observers knew that the other manufacturers of atypical antipsychotics (of which Seroquel is one) were guilty of similar crimes, which would become visible if the opportunity arose for opening up

their marketing records.

The structure of competition in the industry reflects a marketing-inspired adaptation to the existing approval, patent, and prescription systems. Within that broadly systemic but competitively restrictive ecology, pharmaceutical companies develop their own systems of practice to enhance control over the value and distribution of their commodities. These systems are then overseen by company governance structures—Definition Alpha types, which are designed to enhance company-centered goals, such as generating profits. Ethics and the public interest is not necessarily a feature of Alpha governance; they are really just looking out for Alpha.

Our goal should be to design and implement governance of the Definition Beta type—the kind that reflects “a wide range of interests within society”. To accomplish this, we need to understand company and industry practices in a very detailed way. The largest pharmaceutical companies are as wealthy as nations, and far better organized as a purposeful force in the world. Their power is moreover contingent upon their ability to draw on the energy, willingness and participation of those who would be both the instruments and the victims of that power.

I haven’t reviewed the Seroquel documents in any detail. If they are as rich as those of similar cases, they will permit a direct view into how a major pharmaceutical company strategizes to achieve eleven digit revenues from a single drug—and we can be sure, not just in its sale of Seroquel. Lawyers will cherry pick from the documents, looking for evidences of violation of existing laws. Social scientists might better seek out the company norms reflected in the materials, regardless of whether they have specific relation to illegalities.

Further Reading

Applbaum, Kalman. Getting to Yes: Corporate Power and the Creation of a Psychopharmaceutical Blockbuster. Culture, Medicine, and Psychiatry. Feb 27 2009 [Epub ahead of print] Available (by subscription) at: http://www.springerlink.com/content/102869/?Content_Status=Accepted

Fox, Nick and Katie Ward. Global consumption and the challenge to pharmaceutical governance in the United Kingdom. British Medical Journal (2005) 331: 40-42. Available at: http://www.bmj.com/cgi/content/full/331/7507/40.

Michael Steinman et al., Narrative Review: The Promotion of Gabapentin: An Analysis of Internal Industry Documents, Annals of Internal Medicine (2006) 15;145:284-93. Available at: http://www.annals.org/cgi/content/full/145/4/284

AMA citation
. Cases for Overhauling Pharmaceutical Governance. *Somatosphere*. . Available at: . Accessed January 2, 2013.

APA citation
. (). *Cases for Overhauling Pharmaceutical Governance*. Retrieved January 2, 2013, from Somatosphere Web site:

Chicago citation
. . Cases for Overhauling Pharmaceutical Governance. Somatosphere. (accessed January 2, 2013).

Harvard citation
, *Cases for Overhauling Pharmaceutical Governance*, Somatosphere. Retrieved January 2, 2013, from <>

MLA citation
. "Cases for Overhauling Pharmaceutical Governance." . Somatosphere. Accessed 2 Jan. 2013.<>